



4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15AGK;Docket No. CDC-2015-0032]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention, CDC,
Department of Health and Human Services, HHS.

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a new information collection request entitled, "Understanding Barriers and Facilitators to

HIV prevention for Men Who Have Sex with Men (MSM)” to conduct qualitative research with most at risk HIV-negative MSM. The research is intended to understand issues surrounding HIV risk for MSM, identify influences of high risk behaviors and to investigate risk management and resiliency among HIV-negative MSM.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0032 by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.regulation.gov). Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](http://www.Regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.Regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a

proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Understanding Barriers and Facilitators to HIV prevention for Men Who Have Sex with Men (MSM) (Pulse Study) - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)/Division of HIV/AIDS Prevention (DHAP) is requesting approval for one year of a data collection entitled, "Understanding Barriers and Facilitators to HIV prevention for Men Who Have Sex with Men (MSM)." The purpose of this study is to conduct primarily qualitative research with most at risk HIV-negative MSM. There are four goals to this study: (1) Understand issues surrounding HIV risk for MSM; (2) learn more about how gay community or peer norms, and community identification influence risk behaviors; (3) understand individual HIV risk management, such as having an HIV-positive partner with suppressed viral load, barriers and facilitators for use of biomedical interventions (i.e., pre-exposure prophylaxis (PrEP), non-occupational post-exposure prophylaxis (nPEP); and (4) understand factors that promote resiliency among HIV-negative MSM.

The present research will be conducted in the top five

Southern metropolitan areas in the United States with the highest HIV diagnoses for MSM - Atlanta, Georgia; Jackson, Mississippi; Miami, Florida; and New Orleans and Baton Rouge, Louisiana. These cities rank among those in the South with the highest prevalence and incidence of HIV and sexually transmitted infections (STIs) among black/African American and Hispanic/Latino MSM.

The study population will consist of black/African-American and Hispanic/Latino (1) male adolescents who are attracted to men and report they are HIV negative or have not been tested and (2) adult MSM who are recently tested and verified as HIV-negative.

All study participants will be 13 years of age or older. Participants will be recruited in the selected cities through referrals from Health Departments, clinics and other HIV testing centers. In addition, we will recruit via word-of-mouth referrals or flyers given out by community-based, advocacy, faith-based, and service-providing agencies.

Primarily, we will use a qualitative research design and will include a brief quantitative survey to reduce participant burden where possible (for example, when we do not need to know an in-depth answer for socio-demographics, HIV testing history, housing status, health insurance status). The first portion of the interview instrument consists of brief structured questions

to characterize the respondents. The second portion of the instrument consists of open-ended in-depth qualitative questions. This research design was chosen based on the exploratory nature of our study purpose.

All data collection tools will be pre-tested and interviews conducted by trained personnel. The data collection will take place at a time and place that is convenient to the respondent. Locations will be private. Data collection may be audio-recorded and transcribed with the consent of the respondent.

We anticipate that consent forms and screener forms to take five minutes to complete each. We anticipate 50 percent of HIV-negative MSM screened will be eligible for the study. The brief structured survey (15 minutes) and in-depth interview (45 minutes) for HIV-negative MSM are expected to take a total of 60 minutes (1 hour) total. We will complete interviews for 105 black/African-American and 45 Hispanic/Latino HIV-negative MSM at greatest risk for HIV in high prevalence cities in the U.S. South. We anticipate screening 300 potential respondents. The total number of burden hours are 192.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
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General Public-Adults	HIV-negative MSM Screener-English	210	1	5/60	18
General Public-Adults	HIV-negative MSM Screener-Spanish	90	1	5/60	8
General Public-Adults	HIV-negative MSM Contact Information Form-English	105	1	1/60	2
General Public-Adults	HIV-negative MSM Contact Information Form-Spanish	45	1	1/60	1
General Public-Adults	HIV-negative MSM Consent Form-English	95	1	5/60	8
General Public-Adults	HIV-negative MSM Consent Form-Spanish	35	1	5/60	3
General Public-Adults	HIV-negative MSM Assent for Minors Form - English	10	1	3/60	1
General Public-Adults	HIV-negative MSM Assent for Minors Form - Spanish	10	1	3/60	1
General Public-Adults	HIV-negative MSM In-	105	1	1	105

	Depth Interview Guide- English				
General Public- Adults	HIV- negative In-Depth Interview Guide- Spanish	45	1	1	45
Total					192

Leroy A. Richardson,
Chief, Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.

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